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April 24, 2025

VIA ECF

Honorable Renée Marie Bumb
United States District Court
Mitchell H. Cohen Building and
U.S. Courthouse
Courtroom 3D
4th and Cooper Streets
Camden, New Jersey 0810

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower,
Suite 1800
Philadelphia, Pennsylvania 19103

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875 (D.N.J.)**

Dear Chief Judge Bumb and Judge Vanaskie:

Please accept this letter on behalf of the Plaintiffs in advance of the April 28, 2025 case management conference.

1. **ZHP Certificates of Analysis and Material Safety Data Sheets.**

Plaintiffs have reviewed the documents produced by ZHP and intend to serve a 30(b)(6) notice for a corporate representative to provide testimony that can be presented at trial and relied on by experts. This evidence establishes that ZHP was

provided direct notice from a chemical supplier that the solvent DMF used only in the zinc chloride manufacturing process developed by ZHP to reduce the cost and increase the yield of its valsartan API contained Dimethylamine ("DMA"). During the manufacturing process it was the DMA that reacted with the nitrous acid, already known to be a part of the process, to form NDMA.

As the Court is well aware, the COAs and MSDSs and the related documents were required to be produced by ZHP from the outset but were inexplicably held back and not produced by ZHP until recently. Plaintiffs have been severely prejudiced in conducting all fact discovery, expert discovery, expert briefing, and dispositive and trial related motion practice, and preparation for two trials without these documents. It is a certainty that the documents would have been used and referenced throughout.

However, Plaintiffs are not asking that the Court order that discovery and expert work to be repeated. Instead, Plaintiffs request leave to file a motion for sanctions for ZHP's failure to produce these fundamental documents, especially where the ESI Protocol explicitly addresses the production of hard copy documents. Plaintiffs expended significant amounts of time and funds conducting every phase of this case from discovery through two rounds of trial preparation without the ability to utilize these documents. Reimbursement of some or all of those

expenditures, including for attorney time and the associated costs such as for depositions, as well as potentially other relief will be sought on this motion. In this connection, the significance of the violation here is magnified by the fact that ZHP has already been sanctioned for other violations of its obligations during the course of the litigation.

2. DFS Supplements for Wave 2 Cases.

The Parties have agreed that ZHP and Teva will produce amended DFSs for each of the Wave 2 cases by May 2, 2025. The amended DFS will contain testing levels in the form that was done in the *Roberts* case.

3. General Causation Experts for TPP Economic Loss Trial.

Plaintiffs do not believe that any further expert motion practice regarding the general causation experts is necessary or would be an efficient use of the Parties' and the Court's resources. Regardless of whether the Court determines to proceed with the previously scheduled TPP trial or pivot to a consumer class trial, the general causation expert opinions outlined in the Court's Opinion have been fully vetted already.

To set the context, the Court described the applicable benefit of the bargain measure of damages as: "the difference in value between what was bargained for and what was received." (Opinion at 9). The Court provided an overview of the

evidence that will be available to prove value, pointing out that, "the *danger* caused by the contamination – not just the contamination – may result in the drug being worthless," and "determining the danger requires evidence of risk and causation." (*Id.* at 10). The fundamental defect theory described in the Court's Opinion presents a fact question, as the Court found that the drug is not automatically valueless due to contamination or adulteration – the jury decides those questions. (*Id.* at 18-19). Plaintiffs are prepared to provide evidence from their existing experts – and fact testimony – to establish the key elements of the case, including the "bargain" that was paid for, the regulatory context, the criteria to satisfy the definition of adulteration, the requirements for a drug to be sold as a generic/therapeutic equivalent of a brand drug, and most important the risk presented by the nitrosamine contamination.

The Court clearly ruled that "the risk of cancer is what this whole case is about," and that general causation evidence is necessary to establish fundamental defect based on the risk presented: "**[E]vidence of general causation in a TPP trial** cannot be used to establish that any particular individual actually got cancer, it **is directly relevant to the risk presented by the allegedly contaminated VCDs**." (*Id.* at 20 n.14, 46 (emphasis added)). The Court structured the proofs: Plaintiffs can show "the nature and extent of the risks associated with nitrosamine exposure at the

levels found in VCDs. ….Defendants [can] counter with evidence that those risks are minimal or outweighed by the continued therapeutic value of the VCDs." (*Id.* at 20). The jury will weigh the evidence to determine the value of the VCDs received – and whether or to what extent they got the benefit of the bargain. "A jury may very well find that a full refund is appropriate, reasoning perhaps that the risk of cancer causation was so high that it nullified any residual therapeutic value or that even a small risk was unacceptable. On the other hand, the jury may find that any increased risk of cancer was so negligible, attenuated, or insufficiently established through evidence that damages fall far short of a full refund." (*Id.* at 21). More simply put, "Plaintiffs shall have an opportunity to present evidence that the nitrosamine exposure in the VCDs may cause cancer," and "Defendants can, of course, rebut that evidence." (*Id.* at 48).

The general causation experts have already addressed the question of whether the NDMA and NDEA in the contaminated blood pressure pills was capable of causing or contributing to causing cancer in patients ingesting those pills. In other words, the risk posed. The Court considered the Parties' *Daubert* challenges and conducted *Daubert* hearings on March 2, 2022. These experts were listed as potential witnesses for the two TPP trials, in case the Court ruled that general

causation evidence was admissible. Their potential involvement in the trial is nothing new.

Against this backdrop, Defendants take the position that the Court's Opinion should trigger a new round of *Daubert* hearings that will inevitably distract and drain resources and efficiency from the Parties' already concentrated efforts on the preparation of numerous cases for trial, and lead to even more delay. The Parties met and conferred on April 21, 2025, and Plaintiffs attempted to understand the Defendants' position, asking them to explain what issues would need to be addressed at another round of *Daubert* hearings. Defendants could not do so, simply stating over and over that in light of the Court's decision the "fit" of the general causation opinions is questionable. Defendants explained that the general causation opinions were directed to whether the contamination posed a risk of cancer, and the question for the TPP trial is whether the risk of cancer impacts the value. However, as quoted above, the Opinion states that the risk of cancer is fundamental to the jury's determination of value. There is no extra general causation step needed for the jury to make a value finding. Thus, there is no reason to reopen the general causation *Daubert* process.

Plaintiffs queried defense counsel as to how they see this playing out, and the defense was clear that it sees more briefs and motion practice in an effort to prove

that Plaintiffs do not have the necessary experts to "fit" the trial now structured by the Court in the Opinion. Plaintiffs disagree, and note that this argument was made before. In fact, the Court denied Defendants leave to move once again for summary judgment "in light of this Court's decision to require general causation evidence in the TPP Trial." (*Id.* at 48). However, if the Court believes that further expert testimony is needed to connect the general causation evidence to the valuation as a result of the Opinion, Plaintiffs request leave to retain an additional expert or experts to address such a gap. Again, this is not how Plaintiffs read the Court's Opinion, which is clear in delineating the heart of the jury's value judgment – risk vs. benefit – but want to be sure that they can present the necessary experts if the Court does agree with Defendants.

4. Consumer Fraud and Fraud Claims.

Plaintiffs do not believe that the Court's Opinion impacts the available damages in the case, including for the consumer fraud and fraud claims. First, as the Court recognized, the jury may find the TPP Trial Defendants' VCDs to have been so fundamentally defective to have been worthless and award up to full value damages for the warranty, fraud, and consumer fraud claims using Dr. Conti's calculations. (Opinion at 20-21; *see also* 9/10/24 CMC Tr., at 121 (counsel for both parties agreeing that the determination of value – or lack thereof – is for the jury).

In contrast to warranty, the consumer fraud and fraud claims are conduct based, involving affirmative misrepresentations and intentional knowing misrepresentations. The Court recognized the difference at footnote 20 of the Opinion, "Whether Defendants knowingly or fraudulently sold the VCDs as contaminated or otherwise non-cGMP compliant as alleged in Plaintiffs' other claims is a different issue not relevant to Conti's testimony as to the breach of express warranty claim and is, in any event, a jury question." The same point is made at pages 39 and 40 of the Opinion, recognizing that a culpable mental state is not required for a breach of warranty claim. State of mind and affirmative misrepresentations thus distinguish the consumer fraud and fraud claims. In fact, the Court indicated that if Plaintiffs can show a culpable state of mind, that can support a finding that the valsartan was illegally sold. (Opinion at 39).

And the jury may award full value damages for the fraud-based claims regardless of whether they presented a fundamental defect under the benefit of the bargain rubric. In the event the jury finds that Defendants committed actionable inducement fraud or violated consumer fraud statutes (i.e., sold the contaminated VCDs based on actionable misrepresentations), a full reimbursement of the purchase amount is the appropriate remedy. (See Dkt. Nos. 2844, 2869). Courts have recognized that full reimbursement is appropriate where the defendant's

misrepresentations "taint" the purchasing decision of the plaintiff. *See, e.g., FTC v. Figgie Int'l, Inc*., 994 F.2d 595, 606 (9th Cir. 1993) ("The fraud in the selling ... is what entitles consumers ... to full refunds" and explaining that "[t]o understand why [a full refund is appropriate even when the product maintains a modicum of value], we return to the hypothetical of the dishonest rhinestone merchant. Customers who purchased rhinestones sold as diamonds should have the opportunity to get all of their money back. The seller's misrepresentations tainted the customer's purchasing decisions."); *F.T.C. v. BlueHippo Funding, LLC*, 762 F.3d 238, 244 (2d Cir. 2014) (holding that "when an injury by misrepresentation or omission precedes a purchase, the full amount paid by the injured consumer must serve as the baseline for calculating damages because the seller's misrepresentations tainted the customer's purchasing decisions" (internal citations and quotations omitted)); *McGregor v. Chierico*, 206 F.3d 1378, 1388-89 (11th Cir. 2000) (awarding full purchase price damages and stating that "[w]hile it may be true that the defrauded businesses received a useful product, and though less likely, they may have even received the product at a competitive price, the central issue here is whether the seller's misrepresentations tainted the customer's purchasing decisions").

Plaintiffs acknowledge that this line of cases stems primarily from Federal Trade Commission Act case law. However, as this Court itself has recognized,

nearly all of the consumer protection statutes at issue for this TPP Trial contain statutory directives to follow and give due weight to the FTC Act and the interpretations given it by the federal courts in enforcing their own state consumer protection laws. (See Dkt. No. 2694, at 44 (Judge Kugler's summary judgment opinion recognizing that nearly all of the consumer protection states at issue for this trial follow the FTC Act, and Plaintiffs note that Pennsylvania actually does contain and instruction to follow the FTC Act as well)).

Nevertheless, the principle that a fraudulently induced purchase is void *ab initio*, and subject to equitable rescission, is grounded in both common law and common sense. All of the common law fraud jurisdictions recognize equitable rescission as an available remedy where rescission at law is not possible (e.g., for fungible products consumed long before the plaintiff was aware of the cause of action). And further, in cases of inducement fraud, it is equally clear that a defendant should not be permitted to retain any benefit from the fraudulent conduct. *See, e.g., City of Fort Collins v. Open Int'l, LLC*, No. 1:21cv2063, 2024 WL 1239934, at *6-8 (D. Colo. March 21, 2024) (compiling authorities that equity will not permit a defendant to retain a benefit of its own fraud and finding that the defendant was not entitled to claim offset for services it actually provided based on fraudulently induced transaction). In short, allowing these defendants to claim some residual

value for selling contaminated prescription drugs sold under false pretenses provides a windfall to the wrongdoer. This Court recognized the distinction both in its Opinion and at the September 9, 2024 CMC:

> But I think that it matters whether or not there was fraud involved. It just seems to me that if the defendants did not know that these were contaminated at the time, for the plaintiffs to be able to prevail on, well, we should be able to go all the way back and say they were worthless when no one knew they were worthless.
>
> Now, if there was fraud involved, then you're into a different -- you're into fraud territory.

(9/10/24 CMC Tr., at 25.)

In conclusion, if the jury finds that the products were fundamentally defective, the jury may still award up to full damages on the express warranty, fraud, and consumer fraud claims using Dr. Conti's testimony and calculations regarding the computation of damages. In addition, if the jury finds actionable fraud and/or violations of consumer protection statues and finds that the unlawful misrepresentations tainted the TPPs purchasing decisions, the jury may likewise award up to full reimbursement damages.

5. Orders on Motions in Limine.

On April 17, 2025, Plaintiffs sent Defendants slightly revised proposed Orders on the pre-trial motions, accounting for the Court's Opinion in particular with regard to general causation.

On the evening of April 23, 2025, Defendants served their responses to what Plaintiffs had sent, and also served orders on defense motions. Plaintiffs have been able to confirm that some of the language is acceptable, and the Parties have reached agreement on all the language for ZHP's motions in limine (Ex. 1 hereto) and Torrent's motions in limine (Ex. 2 hereto).

The Parties have not reached full agreement with regard to the following Orders:

- Plaintiffs' motions in limine (Ex. 3 hereto)
    - MIL 1: "Defendants cannot assert that it is not appropriate to perform a retrospective analysis of their conduct or the consequences, including for example the resulting adulteration of the contaminated API and VCDs."
    - MIL 2: "Defendants cannot defend their conduct by pointing to lack of knowledge or action by the FDA prior to ZHP's disclosure of the contamination in June 2018, or blame or point the finger at the FDA in any way as a defense or excuse for their conduct."
    - MIL 7: "ZHP Defendants cannot disclose or rely on hearsay discussions with Jinsheng Lin, Ph.D, or other sources, to assert translation or interpretation of the July 27, 2017 email that differs from 30(b)(6) testimony of Min Li, or ZHP's translation."

- MIL 10: "Defendants cannot reference or assert the Valisure Citizen Petition, in any way, including but not limited to with regard to Dr. Najafi, nor can they use the Valisure Citizen Petition to assert that brand diovan contained NDMA or NDEA."
- MIL 16: "Defendants cannot assert the cost of replacement drugs or therapies."
- MIL 18: "Defendants cannot reference, assert, or rely on opinions of defense experts that rely on the precluded opinions of other defense experts. For example, Dr. Afnan's opinions that rely on Dr. Xue's precluded opinions."
- MIL 20: "Defendants cannot argue they are good companies, the "societal benefits" of their VCDs and other products, or the cost of drug research and development."
- MIL 32: "Teva and Torrent cannot argue that they were not responsible for the quality of the API incorporated into their finished dose VCDs."
- MIL 37: "Defendants cannot suggest that there should be set offs for unquantified, speculative subsidies and reimbursements."
- MIL 38: "Defendants cannot reference the dollar amounts for which they sold the API and VCDs, and the amounts of the reimbursements requested and/or agreed to with regard to downstream customers."
- MIL 42: "Defense counsel should be barred from suggesting that they are one in the same as Defendants by using the terms "we," "us," and/or "our" when referring to Defendants. Such statements are irrelevant, inaccurate, and prejudicial."

- Teva's motions in limine

  - Defendants' most recent version of this motion is significantly different from prior versions. As a result, Plaintiffs require more time to review it and propose any edits.

- ZHP's motion to clarify the admissibility of Dr. Afnan's opinions and Plaintiffs' cross motions to exclude his opinions (Ex. 4 hereto)

  - At this time, the Parties have not reached agreement on how to word the exclusion of Dr. Afnan's opinions based on Dr. Xue's excluded opinions.

- Plaintiffs' motions to exclude Dr. Stiroh and Dr. Gibson (Ex. 5 hereto)
    - Plaintiffs are waiting to hear if Defendants agree that the Court has reserved on the Medicare Part D issue.

Plaintiffs stand ready to further discuss the current disputes over the next several days with the defense in the hope that the disputes can be further narrowed.

6. **CMO 38 Product ID Deficiencies.**

   Plaintiffs will be prepared to discuss these at the CMC.

7. **PFS Deficiencies.**

   Plaintiffs will also be ready to address these at the CMC.

Respectfully,

ADAM M. SLATER

Cc: All counsel of record (via ECF)